

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*County of Summit, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Case No. 1:18-OP-45090

*The County of Cuyahoga v. Purdue Pharma  
L.P., et al.*

Case No. 17-OP-45004

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MANUFACTURER DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT  
PLAINTIFFS' STATE-LAW CLAIMS ARE PREEMPTED AND  
THEIR FEDERAL CLAIMS ARE PRECLUDED**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, the Manufacturers<sup>1</sup> respectfully request that this Court grant summary judgment that (1) Plaintiffs' state-law claims are preempted, and their federal claims are precluded, to the extent that they seek to hold the

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<sup>1</sup> "Manufacturers" refers to Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. (incorrectly named as "Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc."), Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Noramco, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc, Cephalon, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc, Mallinckrodt, plc, Mallinckrodt LLC, SpecGx LLC, Allergan Sales, LLC, Allergan USA, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida. Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction, they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges. On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the Daubert motions or summary judgment motions to be filed in the MDL Track One cases.

Manufacturers liable for labeling and marketing opioid medications for the treatment of chronic, non-cancer pain; for failing to advise of additional risks of such use; and for failing to recommend dose and duration limitations; and (2) Plaintiffs' state-law claims are preempted, and their federal claims are precluded, to the extent that they are premised on a theory that the Manufacturers made misrepresentations and omissions to the Drug Enforcement Administration ("DEA") and mislead the DEA into setting artificially high quotes for the permissible sales of opioid medications.<sup>2</sup> This motion will be supported by the pleadings, the record, a Memorandum of Law in Support of Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded (which is simultaneously filed herewith and incorporated by reference herein), the related Summary Sheet, oral argument, and any other evidence requested or permitted by the Court.

**WHEREFORE**, the Manufacturers respectfully request that the Court grant their motion in its entirety and dismiss all of Plaintiffs' claims premised on the preempted or precluded theories of liability with prejudice.

Dated: June 28, 2019

Respectfully submitted,

By: /s/ Jonathan L. Stern

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<sup>2</sup> The arguments supporting this motion relate to FDA and DEA regulatory requirements applicable to, and authorizing various facets of, the finished drug products that are the subject of this litigation. Noramco is an active pharmaceutical ingredient supplier and not a finished drug product manufacturer. Nevertheless, Plaintiffs have lumped Noramco together with J&J and its other affiliated entities, all Marketing Defendants, or all Defendants collectively, even though it did not manufacture, package, brand, market, promote, distribute or sell the finished drug products that are at issue in this litigation. Noramco joins this motion, because federal preemption of claims addressing finished drug products necessarily requires preemption of claims addressing ingredients (manufactured by Noramco) that are incorporated into such products, and because Noramco is subject to an additional layer of FDA requirements authorizing the use and composition of its ingredients and an additional layer of DEA requirements authorizing the quantity of ingredients that it has manufactured.

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 28, 2019, a copy of the foregoing Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded has been served on the Parties, the Court, and the Special Masters pursuant to the Directions Regarding Filing of Briefs Under Seal (ECF No. 1719).

Dated: June 28, 2019

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